

Dockets Management Branch
The Food and Drug Administration
Department of Health & Human Services, Rm. 1-23
12420 Parklawn Dr.
Rockville, MD 20857

Date: 8-23-99

Re: **99P-1340/CP 1** — Petition to, Have *Eternity eau de parfum* declared "Misbranded"

0798 99 SEP - 3 A11:02

Dear Sir or Madam;

In May 1999, the Environmental Health Network (EHN) submitted the above petition to have Calvin Klein's *Eternity eau de parfum* declared "misbranded." I am writing because I fully support this petition and request that the FDA give it **careful** attention with regard to your regulations **21CFR Sec. 740.1, 21CFR Sec. 740.2, and 21CFR Sec. 740.10. Regulation 21CFR Sec. 740.10** states:

- Each **ingredient used** in a cosmetic product and each finished cosmetic product **shall be adequately substantiated for safety** prior to marketing. Any such ingredient **or product whose safety** is not **adequately substantiated prior to marketing** is misbranded unless it contains the **following** conspicuous statement on the **principal display panel**:
- **"Warning — The safety of this product has not been determined."**

As the petition **shows, Eternity contains toxic** ingredients and ingredients whose **safety have not been** substantiated. There **is no warning** label on its packaging.

We all have a right to know **the status** of safety testing of the ingredients in products **such as Eternity** so that we can protect **ourselves and** our families from toxic chemicals, **that** may cause health problems. Most people are not aware **that most** fragrance materials have only limited safety testing. They wrongfully assume these products are safe to **use** in any setting and are surprised when people complain.

Like tobacco smoke, the harmful chemicals currently used in these products **may** affect the health of many people, including: people with asthma, chemical **sensitivities**, chronic fatigue, and other environmental illnesses. Children are particularly vulnerable to toxic chemicals found in products purchased and used by their parents, **caregivers and** teachers. When I am exposed to **fragrance products I can** experience any of the following symptoms based upon the **chemical fragrance** product I encounter:

- | | | | |
|--|---|--|--|
| <input checked="" type="checkbox"/> asthma | <input type="checkbox"/> double vision | <input type="checkbox"/> incoherence | <input checked="" type="checkbox"/> nausea |
| <input type="checkbox"/> anaphylaxis | <input type="checkbox"/> ear pain | <input type="checkbox"/> incontinence | <input type="checkbox"/> nose bleeds |
| <input type="checkbox"/> anxiety, restlessness | <input type="checkbox"/> eczema | <input type="checkbox"/> irritability | <input type="checkbox"/> rashes |
| <input checked="" type="checkbox"/> breathing difficulty | <input type="checkbox"/> eyes, watery or dry | <input checked="" type="checkbox"/> joint aches | <input type="checkbox"/> seizures |
| <input type="checkbox"/> bronchitis | <input checked="" type="checkbox"/> fatigue | <input type="checkbox"/> laryngitis | <input type="checkbox"/> short-term mem. loss |
| <input type="checkbox"/> can't concentrate | <input type="checkbox"/> flushing | <input type="checkbox"/> lethargy | <input type="checkbox"/> sinusitis |
| <input type="checkbox"/> coughing | <input type="checkbox"/> headaches | <input type="checkbox"/> lymph nodes swell | <input checked="" type="checkbox"/> sneezing |
| <input type="checkbox"/> depression | <input checked="" type="checkbox"/> heart beat irregularity | <input type="checkbox"/> mood swings | <input type="checkbox"/> sores, skin/mouth |
| <input type="checkbox"/> disorientation, | <input type="checkbox"/> hives | <input checked="" type="checkbox"/> muscle pain/weakness | <input type="checkbox"/> swallowing difficulty |
| <input type="checkbox"/> dizziness | <input checked="" type="checkbox"/> hypertension | <input type="checkbox"/> nasal congestion | <input type="checkbox"/> tinnitus |
| <input type="checkbox"/> other: _____ | | | |

Please act on behalf of the millions of people who have suffered physical **illness** and injury resulting from **fragrance exposure at work**, at school and in social settings. These **toxic chemicals act** as powerful barriers to **people disabled by asthma** and chemical sensitivities. Toxic **chemicals in fragrances** have **already ruined** countless lives. **Thank you.**

Sincerely,

Carol J. Wagonman
your name

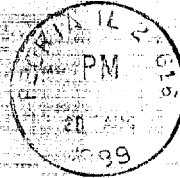
625 N. Coolidge Ct., Peoria, IL 61604
address, city/st/zip

99P-1340

C308

Newsletters and everyone who feels people have a right to know, please copy, share, tell your friends and **WRITE the FDA**, today!

first, fold down

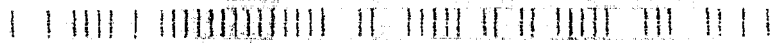


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THE NEW REACTOR

May - June 1999